REMARKS

Written Description

Claims 55-61, 63-93 and 95-99 are rejected under the written description requirement. The examiner maintains that the disclosure of a single plant V-ATPase subunit c isoform 2 promoter from one plant species does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus that comprises plant V-ATPase subunit c isoform 2 promoters.

The objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1991). Also, there is a strong presumption that an adequate written description of the claimed invention is present when the application is field. *In re Wertheim*, 541 F.2d 257, 263, 1919 USPQ 90, 97 (CCPA 1976). Applicants believe the examiner has not overcome this strong presumption.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice. MPEP § 2163, II,A,3,ii. However, what constitutes a "representative number" is an inverse function of the skill and knowledge in the art. MPEP § 2163, II,A,3,ii. Moreover, there may be situations where one species adequately supports a genus. See, e.g., *Rasmussen,* 650 F.2d at 1214, 211 USPQ at 326-27.

Applicants believe description of the V-ATPase, subunit c, isoform 2 promoter from *B. vulgaris* to V-ATPase, subunit c, isoform 2 promoter from *B. vulgaris* is sufficient because a person of ordinary skill in the art knows that the orthologues of a specific gene should possess with very high probability exactly the same function and expression pattern as the specific gene itself. One of ordinary skill in the art should know that the same function and expression pattern of orthologous genes generally results from a strong sequence homology between those orthologous genes, particularly between orthologous genes that are derived only from plants. Therefore, applicants believe there is adequate description even though only one species of the V-ATPase, subunit c, isoform 2 promoter from *B. vulgaris* to V-ATPase, subunit c, isoform 2 promoters was described.

Enablement

Claims 55-99 are rejected under 35 USC § 112, first paragraph, because the specification, while being enabling for DNA constructs comprising the elected promoter of the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO: 1, expressing a heterologous gene, and producing a recombinant protein, does not reasonably provide enablement for DNA constructs comprising plant V-ATPase promoters, or plants, plant cells or protoplasts.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. MPEP § 2164.01 Applicants believe one of ordinary skill in the art would be able to isolated nucleic acid molecules which are

strongly homologous to a known nucleic acid molecule such as SEQ ID NO: 1. How to isolated orthologous sequences is within the knowledge of one of ordinary skill in the art as orthologous genes can be isolated by a simple genomic library screen or by PCR with degenerate primers. Consequently, a person of ordinary skill in the art should also be able to isolate plant orthologues of the *B. vulgaris* V-ATPase, subunit c, isoform 2 promoter by common techniques. Moreover, specific hybridization conditions for isolating strongly homologous genes are disclosed on page 14, lines 18-21 of the specification. The generation of a library is disclosed on pages 15-19 of the specification. Cloning of DNA constructs and the transformation of plant cells with these constructs are known techniques in the state of the art. Applicants disclose cloning of the DNA constructs of the present invention in detail on page 20 ff. and in Figures 1-3. Suitable transformation techniques are disclosed on pages 26ff. In sum, one of ordinary skill in the art would not have to conduct undue experimentation.

Indefiniteness

Claims 55 and 62 were rejected under 35 USC § 112, second paragraph, as being indefinite in the recitation of "functional equivalent." The examiner believes the definition in the specification does not clarify whether "functional equivalent" in claim 55 refers to the promoter or to a DNA construct.

Applicants believe it is to one of ordinary skill in the art what "functional equivalent" is not indefinite, especially in light of the definition in the specification on page 14. One of ordinary skill in the art knows what a functional equivalent of the DNA construct comprising a promoter is. Applicants remind the examiner that breadth of a

claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). Also, some latitude in the manner of expression and aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. MPEP § 2173.02. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement. MPEP § 2173.02.

Claims 55, 61 and 74 are rejected as being indefinite in the recitation of "gene." The examiner believes the definition of "gene" in the specification at page 14 does not limit the claims, as one skilled in the art would interpret "gene" according to its usual and customary meaning. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing ordinary level of skill in the pertinent art at the time the invention was made. Applicants believe the definition of gene as used is claims 55, 61 and 74 is the claim interpretation that would be given by one possessing ordinary level of skill in the art. Therefore, given the definition of "genes" on page 14 of the specification, applicants believe there is no indefiniteness.

Claims 59 is rejected as indefinite in the recitation of "different manner." because the examiner believes claim 59 is indefinite as the manner in which the first and second promoters are regulated cannot be discerned from the claim. The first promoter is the DNA construct comprising the promoter of the plant V-ATPase subunit c in isoform 2 as

claimed in claim 55. The second addition promoter simply has to be regulated in a different manner. Applicants do not see why this should be confusing to one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claim 61 is rejected as being indefinite in the manner of recitation of specific heterologous genes, in the recitation of "a resistance-mediating gene," and in the recitation of "other medicinal, agronomical or other interest." The examiner states that the term "a resistance-mediating gene" would not be understood by one of ordinary skill in the art, as the claim does not specify which type of resistance is mediated. Applicants remind the examiner that breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F2d 689, 169 USPQ 597 (CCPA 1971). The examiner seems to be maintaining the rejection because the applicants do not want to restrict to a narrow definition of "resistance." Here, the mediated resistance can be any type of resistance known in the art.

Claims 74 and 78 are rejected as being indefinite in the recitation of "gene which has been transformed by means of the DNA construct," as it is unclear how a gene would be transformed by a DNA construct, since a DNA construct is a product and not a method or means step. In response applicants point out that the method of claim 75 transforms a plant cell or a protoplast and this transformation is accomplished with the DNA construct claimed in claim 55. Therefore, it is immaterial whether or not the DNA construct is a product.

Claims 96-97 are rejected as being indefinite in the recitation of "which is,"

because it remains unclear whether "which is" refers to a plant cell, a protoplast, or both. "Which is" refers to both a plant cell and a protoplast.

Claims 90 and 91 are rejected as being indefinite because of missing essential steps. The examiner believes claims 90 and 91 are missing the essential step of expressing a recombinant protein. Applicants believe "expressing the DNA construct" produces the recombinant protein. "Expression of DNA" means making protein from DNA.

Claims 92-95 are rejected as missing the essential step of expressing a gene because in the absence of gene expression, the methods of claims 92-95 will not result in the expression of a gene. Applicants disagree with the examiner's position. One of ordinary skill in the art would recognize that the key step is the transformation of the plant with the claimed DNA construct. It is understood that since the preamble states "A method of expression a gene" there would be expression after the transformation.

35 USC § 102

Claims 55-56,58-63, 65-67, 69, 74, 76, 77, 82, 84-85 and 90 are rejected under 35 USC § 102(b) as being anticipated by Struve et al. The examiner believes that the promoter taught by Struve et al. can be considered a functional equivalent of a V-ATPase subunit c isoform 2 promoter, because the promoter function is not specifically limited in the claims and because the definition at page 14 of the specification does not limit the function of the claimed promoter.

Applicants disagree. Anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. *RCA Crop.*

v. Applied Digital Systems, Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Struve et. al. do not disclose each and every element of the claims at issue because the application define the promoter function of a "functional equivalent" of a V-ATPase subunit c, isoform 2 promoter.

The promoter activities of the *B. vulgaris* V-ATPase promoters of subunit A (BVA/70), of subunit c (isoform 1) (BVA/16-1) and of subunit c (isoform 2) (BVA/16-2) are described quantitatively on page 40 in table 3 and Fig. 6-9. Particularly, page 40, lines 18-28 disclose that the V-ATPase promoters of BVA/16-2 and BVA/70 are approximately three times more active than the known CaMV 35 S promoter and that the V-ATPase promoter of BVA/16-1 is 14 more active than the CaMV 35 S promoter. The promoter activity of the commonly used promoter CaMV 35 S is well known in the state of the art. Therefore, it was used as a standard to establish a relative quantification of the three ATPase promoters BVA/16-1, BVA/16-2 and BVA/70.

Also, Fig. 8 and page 43ff show the promoter activities of the specific deletion mutants of the BVA 16-1 and BVA/16-2 promoters in relations to the standard promoter CaMV 35 S. Fig. 9 and page 44 chapter IX show the promoter activities of the three V-ATPase promoters BVA/16-1, BVA/16-2 and BVA/70 in relation to the promoter CaMC 35 S under normal conditions and under salt stress. Fig. 7, page 42ff, and Fig. 9 specify the expression driven by the three V-ATPase promoters BVA/16-1, BVA/16-2 and BVA/70 in different plant parts (root versus leaves) as well as the expression level driven by the three V-ATPase promoters BVA/16-1, BVA/16-2 and BVA/70 during plant development.

The promoter function of the three different plant V-ATPase promoters are disclosed in detail. Since according to page 14, the "activity of a functional equivalent of a plant V-ATPase promoter is similar to that of a plant V-ATPase promoter," the promoter activity/function of a "functional equivalent" is also appropriately defined.

Therefore, applicants respectfully request withdrawal of the 35 USC § 102(b) rejection.

35 USC § 103

Claims 55-99 are rejected as being unpatentable over Struve et al. because examiner maintains that while Struve et al. do not disclose a V-ATPase subunit c isoform 2 promoter, Struve et al. disclose a functional equivalent.

As discussed above, applicants have the promoter activities of "a functional equivalent" and therefore request withdrawal of the 35 USC § 103(a) rejection.

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Respectfully submitted,
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